INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

Date of Review: 07/17/2012

IRO CASE #:

DESCRIPTION OF THE SERVICES OR SERVICES I

Appeal Skelaxin 800 mg quantity 90 90862

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Anesthesiology/Pain Management

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

1. Urine drug screen results
2. Medication records 1/11/08-4/3/12
3. Clinical records Dr. 2/5/08
4. Clinical records Dr. 3/4/08
5. Chronological review dated 04/21/08
6. Peer review dated 05/09/08
7. Clinical records Dr. 7/9/08-5/2/01
8. IME report dated 10/22/08
9. Clinical records Dr. 6/15/09-4/18/11
10. Peer review dated 10/16/09, 3/23/11
11. Medication reviews 4/16/10
12. Clinical records Dr. 8/26/11-5/3/12
13. Utilization review determination dated 06/07/12
14. Utilization review determination dated 06/20/12

PATIENT CLINICAL HISTORY [SUMMARY]: The patient has a date of injury of xx/xx/xx.

Records indicate that the patient has a history of chronic low back pain. He is reported to be status post an L4-5 laminectomy in 1974 and bilateral L4-5 hemilaminectomies performed on 08/26/92. Records indicate that the claimant has been treated with oral medications, physical therapy, and interventional procedures. It is noted that on *05/03/0*2 the claimant underwent a redo bilateral L4-5 hemilaminectomy, and discectomy with extension of hemilaminotomies from the L3 through S1 levels. When seen in follow-up on 06/06/02 the patient was noted to have a right L5 radiculopathy which was resolved but had a post-op L5 radiculopathy with a left sided drop foot. The records indicate that the patient is being followed by pain management specialists and no further surgical interventions were recommended.

The most recent clinic note indicates that the patient is currently under the care of Dr. . The claimant was seen in follow-up on 05/02/12. At this time he is noted to be 72 inches tall and weigh 219 pounds. He continues to have low back and left lower extremity pain. He is noted to be on methadone every eight hours which provides him a smoother pain control response. He does not report any side effects from the medication. It is noted that there appears to be trouble with his Skelaxin prescription. It is reported that the carrier is saying Skelaxin should only be used for short term. On examination he is noted to be stable. Dr. notes that it is appropriate to use muscle relaxants for long term muscle spasms in patients who have post laminectomy syndrome.

The record contains a letter of appeal dated 06/28/12 in which it is reported that the patient's pain is related to muscle spasm. He is noted to have been on Soma in the past which was effective. However, this was discontinued by Worker's Compensation so he was subsequently switched to Skelaxin. It is reported that Skelaxin is effective. He is noted to have had allergies to Zanaflex, Flexeril, Lyrica, and Cymbalta.

The initial review was performed on 06/07/12 by Dr.. Dr. non-certified the request noting that the guidelines recommend muscle relaxants only for short treatment of acute exacerbations in patients with chronic low back pain. He further notes that the recent medical records did not include a comprehensive physical examination of the lumbar spine documenting muscle spasms for which the requested medication is indicated. He notes that there has been no significant improvement in the patient's pain level despite medication use as noted in the latest reports provided. He subsequently finds that medical necessity was not established.

The appeal request was reviewed on 06/20/12 by Dr.. Dr. non-certified the request. He notes as previous peer review of this request indicated there has been no significant improvement in patient's pain level despite medication use. In addition recent clinical records do not include comprehensive physical examination of lumbar spine documenting muscle spasm on physical examination. He notes there is no indication of objective functional improvements in clinical documentation. The patient's pain level is 7/10. He notes the guidelines recommend non-sedating muscle relaxants with caution as second line option for short term treatment of acute low back pain and for short term treatment of acute exacerbations of pain associated with chronic low back pain. He notes the claimant has been utilizing Skelaxin since 08/20/11 which indicates the medication is being utilized for more short term treatment of acute exacerbation. He subsequently upholds the previous denial and non-certified the request.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

The request for Skelaxin 800 mg quantity 90, 90862 is not supported as medically necessary, and prior utilization review determinations are upheld. The submitted clinical records indicate the claimant has a failed back surgery syndrome with chronic low back and left lower extremity pain. The submitted clinical records do not provide a current detailed physical examination which would establish the claimant has active lumbar myospasms for which the claimant's Skelaxin would be clinically indicated. The ODG provides no provision for using muscle relaxants prophylactically. As noted by prior reviewers, ODG does not support the chronic use of muscle relaxers in treatment of low back pain. Therefore, based on submitted clinical information, the request does not meet ODG guidelines and would not be supported as medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

The 2012 Official Disability Guidelines, 17th edition, The Work Loss Data Institute. Online edition.

Muscle relaxants (for pain)

Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) See the Low Back Chapter. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Schnitzer, 2004) (Van Tulder, 2004) (Airaksinen, 2006) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a recent review in *American Family Physician*, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)

Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006)

ANTISPASTICITY DRUGS: Used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries (upper motor neuron syndromes). Associated symptoms include exaggerated reflexes, autonomic hyperreflexia, dystonia, contractures, paresis, lack of dexterity and fatigability. (Chou, 2004)

Baclofen (Lioresal®, generic available): The mechanism of action is blockade of the pre- and post-synaptic $GABA_B$ receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)

Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment.

Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to a maximum dose of 80 mg a day. (See, 2008)

Dantrolene (Dantrium®, generic available): Not recommended. The mechanism of action is a direct inhibition of muscle contraction by decreasing the release of calcium from the sarcoplasmic reticulum.

Side Effects: A black-box warning has been issued about symptomatic fatal or nonfatal hepatitis.

Dosing: 25 mg a day for 7 days, 25 mg three times a day for 7 days, 50 mg three times a day for 7 days and then 100 mg three times a day. (See, 2008)

ANTISPASMODICS: Used to decrease muscle spasm in conditions such as LBP although it appears that these medications are often used for the treatment of musculoskeletal conditions whether spasm is present or not. The mechanism of action for most of these agents is not known. (Chou, 2004)

Cyclobenzaprine (Flexeril®, Fexmid™, generic available, ER as Amrix®): Recommended for a short course of therapy. Immediate release (eg, Flexeril, generic) recommended over extended release (Amrix) due to recommended short course of therapy (also note substantial increase in cost for extended release without corresponding benefit for short course of therapy). Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis

concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) A recent RCT found that time to relief was better with immediate release compared to extended release cyclobenzaprine. (Landy, 2011)

Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004)

Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. (See, 2008)

Methocarbamol (Robaxin®, Relaxin™, generic available): The mechanism of action is unknown, but appears to be related to central nervous system depressant effects with related sedative properties. This drug was approved by the FDA in 1957.

Side Effects: Drowsiness, dizziness and lightheadedness.

Dosing: 1500 mg four times a day for the first 2-3 days, then decreased to 750 mg four times a day. (See, 2008)

Metaxalone (Skelaxin®, generic available) is reported to be a relatively non-sedating muscle relaxant. The exact mechanism of action is unknown, but the effect is presumed to be due to general depression of the central nervous system. Metaxalone was approved by the FDA in 1964 and data to support approval were published in the mid-1960s. (Toth, 2004)

Side Effects: Dizziness and drowsiness, although less than that compared to other skeletal muscle relaxants. Other side effects include headache, nervousness, nausea, vomiting, and GI upset. A hypersensitivity reaction (rash) has been reported. Use with caution in patients with renal and/or hepatic failure.

Dosing: 800 mg three to four times a day (See, 2008)

Chlorzoxazone (Parafon Forte®, Paraflex®, Relax™DS, Remular S™, generic available): this drug works primarily in the spinal cord and the subcortical areas of the brain. The mechanism of action is unknown but the effect is thought to be due to general depression of the central nervous system. Advantages over other muscle relaxants include reduced sedation and less evidence for abuse. (See, 2008)

Side Effects: Drowsiness and dizziness. Urine discoloration may occur. Avoid use in patients with hepatic impairment.

Dosing: 250-750 mg three times a day to four times a day.

Carisoprodol (Soma®, Soprodal 350™, Vanadom®, generic available): Suggested for use as an adjunct to rest, physical therapy, analgesics, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. (AHFS, 2008) A 250 mg formulation was FDA approved in 9/07 for treatment of acute, painful musculoskeletal conditions such as backache. Neither of these formulations is recommended for longer than a 2 to 3 week period. Carisoprodol is metabolized to meprobamate an anixolytic that is a schedule IV controlled substance. Carisoprodol is classified as a schedule IV drug in several states but not on a federal level. It is suggested that its main effect is due to generalized sedation as well as treatment of anxiety. This drug was approved for marketing before the FDA required clinical studies to prove safety and efficacy. Withdrawal symptoms may occur with abrupt discontinuation. (See, 2008) (Reeves, 2003) For more details, see Carisoprodol, where it is “Not recommended.” See also Weaning of medications.

Side Effects: drowsiness, psychological and physical dependence, & withdrawal with acute discontinuation.

Dosing: 250 mg-350 mg four times a day. (See, 2008)

Orphenadrine (Norflex®, Banflex®, Antiflex™, Mio-Rel™, Orphenate™, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959.

Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. (Shariatmadari, 1975)

Dosing: 100 mg twice a day; combination products are given three to four times a day. (See, 2008)

ANTISPASTICITY/ANTISPASMODIC DRUGS:

Tizanidine (Zanaflex®, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. (Malanga, 2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with subacute and chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007)

Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTs should be monitored baseline, 1, 3, and 6 months). (See, 2008)

Dosing: 4 mg initial dose; titrate gradually by 2 – 4 mg every 6 – 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. (See, 2008) Use with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic aminotransaminase elevations that are usually asymptomatic and reversible with discontinuation. This medication is related to clonidine and should not be discontinued abruptly. Weaning should occur gradually, particularly in patients that have had prolonged use. (Zanaflex-FDA, 2008)

Benzodiazepines: Not recommended due to rapid development of tolerance and dependence. There appears to be little benefit for the use of this class of drugs over nonbenzodiazepines for the treatment of spasm. (See, 2008) See Benzodiazepines.